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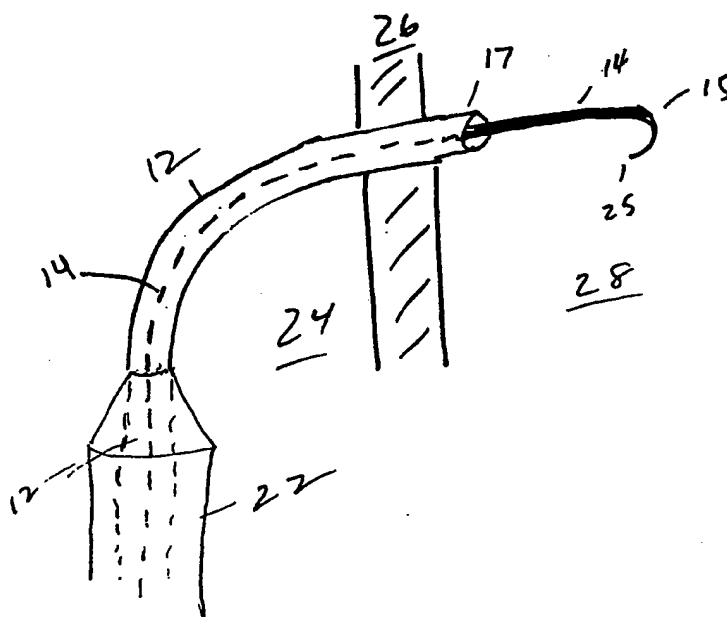
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(54) Title: **TRANSSEPTAL PUNCTURE APPARATUS**



(57) Abstract: Devices and methods for performing a transeptal puncture procedure are described. In certain embodiments, the device includes a blunt outer needle (12), and a second inner needle (14) disposed longitudinally through the lumen (13) of the outer needle (12), wherein the inner needle (14) is flexible, e.g., has a flexible portion and/or a bend or other non-traumatic conformation at its tip.

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TRANSSEPTAL PUNCTURE APPARATUS

Related Applications

[0001] This application claims priority to and the benefit of U.S.S.N. 60/517,983, filed November 6, 2003, the contents of which are incorporated by reference herein.

Field of the Invention

[0002] The invention generally relates to a device for performing an intracardiac transseptal puncture procedure. More specifically, the device relates to transseptal puncture of the atrial septum for the treatment of intracardiac defects such as patent foramen ovale (PFO) and other therapeutic applications for diseases associated with the heart.

Background of the Invention

[0003] Septal puncture is utilized in patients in which a communication is present between the two atria of the heart, for example, a patient with a patent foramen ovale (PFO). A PFO consists of two layers of overlapping but unfused tissues, the septum primum and the septum secundum, forming a tunnel like "hole" between the two tissues that can put the patient at a high risk of embolic stroke. Due to the tunnel-like nature of many PFOs, an occlusion device that is used to repair the PFO often does not sit flat on the septal wall when it is implanted, such that a portion of the occluder is positioned in the PFO tunnel. For this reason a second hole in the septum primum part of the atrial septum near the PFO is introduced by septal puncture through which the occlusion device is then positioned (rather than through the PFO tunnel).

[0004] Septal puncture through an intact atrial septum from the right atrium to the left atrium is also often necessary. This is traditionally performed using rigid, long needles, such as

Brockenbrough or Ross needles. In all types of septal puncture, the needle that is used to puncture the atrial septum poses a high risk of inadvertent puncture through tissue other than the septum primum, for example, the atrial free wall, posing a significant risk to the patient. For PFO closure, this risk is potentially even higher, due to the fact that the septal tissue is defective and often thinning, and may stretch an even greater amount during the puncture procedure, bringing the tip of the needle dangerously close to the atrial free wall or the left atrial appendage.

[0005] A device and method that permits the surgeon to safely puncture both an intact atrial septum and an atrial septum having a PFO is therefore needed.

Summary of the Invention

[0006] The invention relates generally to devices and methods for performing a transseptal puncture procedure that are safe alternatives to those currently being performed.

[0007] In one aspect, the invention relates to a device for puncturing the atrial septum of a patient. In one embodiment of the invention, the device includes a first, outer needle with a blunt distal end and a lumen longitudinally disposed therethrough and a second, inner needle axially disposed in the lumen of the outer needle. In an embodiment, the inner needle has a proximal portion, an intermediate portion, and a distal portion, wherein the intermediate portion is more flexible than either the proximal portion or the distal portion of the inner needle.

[0008] In an embodiment, the intermediate portion is a segment that is approximately 20 mm from the distal end of the inner needle. The intermediate portion may be, for example, 3 mm in length. In an embodiment, the intermediate portion has a waist. The waist of the intermediate portion is, for example, about 0.2 mm in diameter. In a particular embodiment, the intermediate portion of the inner needle may be made of a polymer.

[0009] In another embodiment, the inner needle has a distal portion and a proximal portion, wherein the distal portion is more flexible than the proximal portion. In another embodiment, the inner needle is flexible in both the distal portion and the proximal portion (e.g., has homogeneous flexibility).

[0010] As another feature, the distal portion of the inner needle has a distal portion that deviates from the linear path of the inner needle such as, for example, a taper, a bend, a curve, a cork screw or a hook. In a particular embodiment, the tip of the inner needle is turned inward during the delivery procedure to avoid the risk of inadvertant puncture of tissue. In another embodiment, the inner needle contains a portion that has a different thickness or diameter than the rest of the inner needle such as, for example, a tapered portion, whereby the inner needle is tapered from one thickness to another.

[0011] In an embodiment, the distal portion of the outer needle is more flexible than the proximal portion of the outer needle.

[0012] In still another embodiment, the device includes a outer needle with a blunt distal end and a lumen axially disposed therethrough and a pump for introducing a high pressure jet spray through the lumen of the outer needle.

[0013] In a further embodiment of the invention, the device has a outer needle with a blunt distal end and an insulating material for insulating the length of the proximal and intermediate portion, leaving the distal tip of the outer needle uninsulated. As an additional feature, the device may include unipolar electrodes or, alternatively, the device may include bipolar electrodes.

[0014] In another aspect, the invention provides a method for puncturing the atrial septum of a patient's heart by accessing the right atrium via a vessel. The method includes introducing into the right atrium a transseptal puncture device that includes a first outer needle with a blunt distal

end and a lumen longitudinally disposed therethrough and a second inner needle axially disposed in the lumen of the outer needle, the inner needle having a proximal portion, a distal portion, and an intermediate portion that is more flexible than the proximal portion or the distal portion. The outer needle is contacted with the atrial septum and the inner needle is pushed through the septum in advance of the outer needle. A delivery sheath is then positioned using a standard catheterization laboratory technique in the left atrium and the transseptal puncture device is withdrawn from the patient's body.

[0015] In another aspect, the invention provides a method for puncturing the atrial septum of a patient's heart by accessing the right atrium via a vessel. The method includes introducing into the right atrium a transseptal puncture device that includes a first, outer needle with a blunt distal end and a lumen longitudinally disposed therethrough and a second, inner needle axially disposed in the lumen of the outer needle, the inner needle having a proximal portion and a distal portion, wherein the distal portion is more flexible than the proximal portion. The outer needle is first contacted with the atrial septum. The inner needle is then pushed through the septum in advance of the outer needle. A delivery sheath is positioned in the left atrium and the transseptal puncture device is withdrawn from the patient's body.

Brief Description of the Drawings

[0016] In the drawings, like reference numbers generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

[0017] Figure 1 is a plan view of a transseptal puncture device according to an illustrative embodiment of the invention.

[0018] Figure 2 is a longitudinal plan view of the distal end of a transseptal puncture device according to an illustrative embodiment of the invention.

[0019] Figure 3 is a cross sectional view of the distal end of a transseptal puncture device taken along lines 3-3 in Figure 2.

[0020] Figure 4A is a longitudinal view of the distal end of an inner needle of a transseptal puncture device according to an illustrative embodiment of the invention in which the intermediate portion contains a waist.

[0021] Figure 4B is an exploded view of the intermediate portion of Figure 4A.

[0022] Figure 5 is a longitudinal view of the distal end of an inner needle of a transseptal puncture device according to another illustrative embodiment of the invention in which the inner needle has a tapered intermediate portion.

[0023] Figure 6 is a longitudinal view of the distal end of an inner needle of a transseptal puncture device according to another illustrative embodiment of the invention, in which the inner needle has an intermediate portion.

[0024] Figure 7 is a longitudinal view of the distal end of an inner needle of a transseptal puncture device according to another illustrative embodiment of the invention in which the distal tip of the inner needle is bent.

[0025] Figure 8 is a longitudinal view of the distal end of an inner needle of a transseptal puncture device according to another illustrative embodiment of the invention in which the distal end of the inner needle has a hook.

[0026] Figure 9a-9g depicts the steps in an illustrative method for puncturing an atrial septum with an illustrative transseptal puncture device according to the invention.

[0027] Figure 10 is a fragmented illustration of a septal puncture apparatus according to an illustrative embodiment of the invention.

[0028] Figure 11 is a schematic side view of a portion of a septal puncture apparatus including a set of flexible members according to an illustrative embodiment of the invention.

[0029] Figure 12A is a schematic side view of a portion of an embodiment of a septal puncture apparatus including a set of flexible members partially extended from an elongate member.

[0030] Figure 12B is a schematic side view of the flexible members of Figure 12A fully extended from the opening in the elongate member.

[0031] Figure 13 is a schematic side view of another embodiment of a set of flexible members according to the invention.

[0032] Figure 14A is a schematic side view of an embodiment of a flexible member according to the invention.

[0033] Figure 14B is a schematic end-on view of the flexible member of Figure 14A.

[0034] Figure 15A is a schematic side view of an embodiment of a flexible member according to the invention.

[0035] Figure 15B is a schematic end-on view of the flexible member of Figure 15A.

[0036] Figure 16A is a schematic side view of an embodiment of a set of flexible members, a cutting member, and an elongate member of a portion of a septal puncture apparatus according to the invention.

[0037] Figure 16B is an illustration of the set of flexible members and the cutting member extended out of the elongate member of Figure 16A.

[0038] Figure 17 is a partially broken-away view of a heart depicting a portion of a septal puncture apparatus, according to the invention, on a second side of the septal wall.

[0039] Figure 18A is a cross-sectional view of a septal wall of a heart depicting a set of flexible members located outside an opening in an end of an elongate member, according to an illustrative embodiment of the invention.

[0040] Figure 18B is a cross-sectional view of the flexible members of Figure 19A in which a portion of the flexible members is located in contact with a first side of a septal wall and another portion of the flexible members is located in proximity to a second side of the septal wall.

[0041] Figure 18C is a cross-sectional view of the flexible members of Figures 19A and 19B in which a cutting member is extended from a lumen in the delivery member creating a hole through the septal wall.

[0042] Figure 19 is a schematic side view of a flexible member, a cutting member, and an elongate member according to an illustrative embodiment of the invention.

Detailed Description of the Invention

[0043] The invention described herein relates to devices and methods for puncturing the atrial septum via the percutaneous route for the treatment of intracardiac defects such as, for example,

patent foramen ovale, intracardiac sources of emboli that may cause embolic stroke, and defects related to cardiac disease.

[0044] In one aspect, the invention relates to a percutaneous device for making a transseptal puncture in the atrial septum of the heart. Figure 1 is a plan view of the transseptal puncture device according to an illustrative embodiment of the invention. The illustrative percutaneous device 10 includes a first, outer needle 12 including a lumen 13 axially disposed along the long axis of the outer needle 12 and including a blunt distal end 17 having an opening 18. A second, inner needle 14 is axially disposed within the lumen of the outer needle 12. The outer needle 12 provides structural support for the inner needle 14 and also functions as a dilator of the hole created in the atrial wall by the inner needle 14. The device 10 may further feature a transcutaneous intravascular sheath 22 through which the device 10 passes from outside the patient's body through a vessel, for example, the femoral vein, through the inferior vena cava to the right atrium, and a control handle 26 at the distal end 27 of the sheath 22. The sheath and/or other components of the delivery system may be steerable by actuators (not shown) on the control handle 26 to aid in delivering the device along the tortuous vascular path leading to the patient's right atrium. In certain embodiments, the distal end 17 of the outer needle 12 is tapered toward the inner needle 14, and the distal end 27 of the sheath 22 is tapered toward the outer needle 12.

[0045] In an embodiment, the outer needle 12 is similar in size to a Brockenbrough needle, *e.g.*, with tip diameter of about 0.8 mm. The percutaneous device 10 also features a septal perforator, for example, a second, inner needle 14. Alternatively, the septal perforator is a radio frequency electrode (not shown) that is coupled to the outer needle 12, or is a high pressure jet spray (not shown) that is emitted from the opening 18 of the outer needle 12.

[0046] In an embodiment depicted in Figures 2 and 3, the inner needle 14 includes a sharp tip 25 at a distal end 15 of the inner needle 14. The inner needle 14 is axially disposed within the lumen 13 of the outer needle 12. The inner needle 14 is reciprocally and axially moveable in the lumen 13 of the outer needle 12. The inner needle 14 can be rotated as well. The distal end 15 of the inner needle 14 is extendable through the opening 18 at the distal end 17 of the outer needle 12. The inner diameter of the lumen 13 of the outer needle 12 typically approximates the outer diameter of the inner needle 14.

[0047] The outer needle 12 and the inner needle 14 are made from various metals such as, for example, nitinol, steel, or titanium, or alloys thereof or polymers such as polyimide, PEBAX®, polyethylene, polytetrafluoroethylene (EPTFE), Fluorinated ethylene propylene (FEP), and polyurethane. In one embodiment, the inner needle 14 is solid to increase its sharpness. Alternatively the inner needle 14 is hollow. The use of the outer needle 12 for introducing the inner needle 14 into the patient's cardiac tissue is preferred. In another embodiment, a dilator that is made from material that provides sufficient support during the transeptal puncture procedure is used and the outer needle 12 may not be needed.

[0048] Figure 4A and 4B are a longitudinal view and an exploded view, respectively, of the distal end of an inner needle of a transeptal puncture device according to another illustrative embodiment of the invention. The illustrative inner needle 14 includes a waist 30 near the distal end 15 of the inner needle 14. The waist 30 is positioned on an intermediate portion 16 of the inner needle 14 that is narrower in diameter than the portion of the inner needle 14 that is proximal to the intermediate portion 16 and the portion of the inner needle 14 that is distal to the intermediate portion 16. The waist 30 is thereby more flexible or bendable than the portions of the inner needle 14 that are proximal or distal to the waist 30. In one embodiment, the distal portion 15 is more flexible than the proximal portion 11 of the inner needle 14. The intermediate

portion 16 having waist 30 is positioned about 5 mm to about 30 mm, preferably about 20 mm proximal to the distal end 15 of the inner needle 14. In an embodiment, the diameter of the waist 30 ranges from about 0.1 mm to about 0.5 mm, *e.g.*, if the waist is composed of a metal, while the diameter of the inner needle 14 proximal to the waist 30 ranges from about 0.5 mm to about 1.5 mm and the diameter of the inner needle 14 distal to the waist 30 ranges from about 0.2 mm to about 1 mm. In another embodiment, the diameter of the waist 30 ranges from about 0.1 to about 1 mm, *e.g.*, if the waist is composed of a non-metal, such as, for example, a polymer, such as (PEBAX) or polyurethane, a plastic, rubber, or any other polymer deemed suitable to those skilled in the art. In that case, the diameter of the inner needle 14 proximal to the waist 30 ranges from about 0.5 mm to about 3.0 mm and the diameter of the inner needle 14 distal to the waist 30 ranges from about 0.2 mm to about 3.0 mm. For example, the diameter of the waist 30 is about 0.2 mm, the diameter of the inner needle 14 proximal to the waist 30 is about 1 mm and the diameter of the inner needle 14 distal to the waist 30 is about 0.4 mm.

[0049] Figure 5 is a longitudinal view of the distal end of an inner needle of a transseptal puncture device according to another illustrative embodiment of the invention. In one embodiment, the inner needle 14 diameter is larger (*e.g.*, 1 mm larger) at the proximal end of the inner needle 14 than the distal end 17. Alternatively, the inner needle 14 diameter is larger throughout the length of the inner needle 14 except for the most distal about 20 mm of the distal end 15. In one embodiment, the inner needle 14 contains a portion 31 at the distal end 15 that is tapered or the diameter of the inner needle 14 is gradually stepped down, for example, to a diameter of about 0.1 to about 0.25 mm, preferably about 0.2 mm, at a point "A" about 10 mm to about 20 mm proximal to the tip 25 of the inner needle 14. In an embodiment, the diameter of the inner needle 14 from the tip 25 to the point "A" is uniform. In a particular embodiment, the distal about 10 mm of the inner needle 14 adjacent to the tip 25 has a diameter of about 0.2 mm.

According to this embodiment of the invention, the distal end 15 of the inner needle 14 is thinner and therefore is more flexible than the proximal portion 11 of the inner needle 14. In another embodiment the tapered or step-down portion 31 can extend to the tip 25 of the inner needle 14 and can be about 5mm to about 30 mm long.

[0050] Figure 6 is a longitudinal view of the distal end of an inner needle of a transseptal puncture device according to another illustrative embodiment of the invention. At a position about 5 mm to about 30 mm, preferably about 20 mm from the distal end 15, the inner needle 14 includes an intermediate portion 16 manufactured from, or coated with, a material or treated such that the intermediate portion 16 is more likely to bend than the portions of the inner needle 14 that are proximal 11 and distal 15 to the intermediate portion 16. For example, if the inner needle 14 is composed of nitinol, the intermediate portion 16 may be annealed at 500 degrees Centigrade for 10 minutes to relieve stress in otherwise superelastic nitinol wire in an as drawn condition. Alternatively, the intermediate portion 16 may be made from a softer material than the proximal portion 11 and distal portion 15 of the inner needle 14. For example, the material of the intermediate portion 16 may be a polymer while the proximal portion 11 and distal portion 15 on the inner needle 14 are made from, for example, a rigid metal or, alternatively, a nickel titanium alloy such as nitinol. The intermediate portion 16 may be welded to, crimped or attached by adhesives to the proximal portion 11 and distal portion 15 of the inner needle 14. In one embodiment, the intermediate portion 16 is about 0.5 mm to about 30 mm, preferably about 2 mm in length. Alternatively, geometric modification may make the intermediate portion 16 more flexible, for example, by the introduction of slits, grooves, cut-aways, notches, dimples, or other modification that thins portions of the wall of the intermediate portion 16.

[0051] In another embodiment (not shown), the distal, the proximal, and/or the intermediate portion (if present) of the inner needle 14 is flexible.

[0052] Figure 7 is a longitudinal view of the distal end of an inner needle of a transseptal puncture device according to another illustrative embodiment of the invention. The distal end 15 of the illustrative inner needle 14 may be straight (e.g., 0 degrees) or is bent at an angle ranging from about >0 degrees to about 270 degrees, preferably about 180 degrees relative to the long axis of the inner needle 14.

[0053] Alternatively, referring to Figure 8, when the distal end 15 of the inner needle 14 is not constrained within the lumen 13 of the outer needle 12, the distal end 15 has an essentially non-traumatic conformation, such as a helical, curved, cork screw, or hook shape. For example, the diameter "B" of the loop that forms the hook 32 can be between about 5 mm and about 30 mm, preferably about 10 mm. When the distal end 15 is enclosed within the lumen 13 of the outer needle 12, the entire length of the inner needle 14 is substantially straight and parallels the long axis of the outer needle 12.

[0054] In an alternative embodiment of the transseptal puncture device, the inner needle is replaced by a pulsating high pressure saline jet (or other suitable fluid) (not shown) generated by a pump. The jet spray is directed to the atrial septum from the distal end of the blunt, outer needle according to the invention and incises the tissue. The outer needle is then gradually advanced through the incision. Because the incision is made gradually and slowly, the method is safer than the currently used methods, for example, because there is a reduced risk of trauma and/or bleeding.

[0055] In yet another embodiment of the transseptal puncture device, the blunt, outer needle is replaced by a radio frequency (RF) apparatus (not shown). The outer needle according to the invention is insulated except for the outer needle tip. The alternating current travels down the outer needle. Preferably, unipolar electrodes can be used for the outer needle with grounding pads typically placed on the patient's thighs. Alternatively, a bipolar electrode system can be

employed as well. The application of RF to the outer needle increases the tissue temperature around the outer needle tip to over 100 degrees C. Mechanical cohesion in the tissue is diminished and allows the outer needle to be advanced as pressure is applied to the tissue by the outer needle tip. Any other method producing heat (e.g., such as electrical resistance, laser, or ultrasound) can be potentially used instead of RF. As with the saline jet described above, the incision is created slowly therefore the risk of accidental puncture of tissue that is not targeted for incision is minimal.

[0056] In another aspect, the invention provides a method using a percutaneous approach for puncturing the atrial septum of a patient to treat, for example, patent foramen ovale or to gain access to the left atrium to ablate the left atrial appendage. Figures 9A-9E depict the steps of an illustrative method for puncturing an atrial septum with the transseptal puncture device according to the invention. The illustrative method includes the step of introducing an intravascular sheath 22 in a vessel to access the lumen of the right atrium 24. In an embodiment, the sheath 22 is tapered to enhance advancement of the sheath 22 through the atrial septum 26. Referring to Figure 9A, after the sheath 22 is properly positioned in the right atrium 24, the outer needle 12 of the transseptal device 10 is advanced distally toward the atrial septum 26 and positioned against septum primum 26a at the puncture site. The blunt distal end 17 of the outer needle 12 is then pushed against septum primum 26a until some tenting of the atrial septum 26 is visible. The tenting should be sufficient to correctly identify the puncture site in the septum primum 26a. Alternatively, visualization techniques such as, three-dimensional echocardiogram or magnetic resonance imaging can be used that may work without tenting. Some amount of tenting also assists with the puncture itself.

[0057] Referring to Figure 9B, once the outer needle 12 is positioned, the inner needle 14 is advanced relative to the outer needle 12 through the septum 26. At its most distal position,

about 10 mm of the inner needle 14 should extend from the distal end 17 of the outer needle 12. Alternatively, the most distal position could be about 30 mm, if the distal portion 15 of the inner needle 14 had a hook shape, as is shown in Figure 8. In an embodiment, the transition from the hook portion to the straight portion of the inner needle 14 is exposed. The outer needle 12 follows the path of the inner needle 14 through the septum 26. Because of the fine diameter, extreme sharpness, and the added stiffness provided by the outer needle 12, the inner needle 14 can be initially advanced into the septum 26. The motion of the inner needle 14 may be forward, vibrating, reciprocating, linear, or rotational, for example. In one embodiment, movement of the inner needle 14 is accomplished manually. Alternatively, movement of the inner needle 14 may be automated and therefore require additional controls such as a spring-loaded needle to be attached to the delivery system components such as the sheath 22. Such devices of the invention are easier for the doctor to manipulate and safer for the patient.

[0058] Referring now to Figure 9C, once the distal end 15 of the inner needle 14 is positioned within the septum 26, the tissue provides support to the exposed part of the inner needle 14 until the whole tip of the inner needle 14 is delivered into the left atrium 28. Referring to Figure 9D, the outer needle 12 is advanced and positioned in the left atrium 28. Referring to Figure 9E, standard catheterization laboratory procedures are utilized to place the sheath 22 within the left atrium 28. Once the sheath 22 is in the left atrium 28, the other components of the device, for example, the inner needle 14 and the outer needle 12, can be completely removed from the sheath 22 and the sheath 22 can be used to deliver implants, for example, such as an atrial occluder for the treatment of a patent foramen ovale, sutures, or other intracardiac therapeutic devices. For example, referring to Figure 9F, one half of an occluder 30 is released from the sheath 22 and positioned in the left atrium 28. Referring to Figure 9G, the sheath 22 is then withdrawn into the right atrium 24 and the other half of the occluder 30 is released and

positioned in the right atrium 24. In an embodiment, the inner needle 14 is left behind, traversing the puncture site, and acts to maintain the puncture site as well as to act as a guidewire (*e.g.*, and the other outer needle 12 is withdrawn). In another embodiment, the inner needle 14 is withdrawn, *e.g.*, into the outer needle 12.

[0059] The method for transseptal puncture using the transseptal device described herein is advantageous over conventional methods. For example, when using the devices and methods of the invention inadvertent contact of the inner needle 14 with the left atrial free wall (not shown) immediately after the septum 26 is punctured does not result in damage to or perforation of the left atrial free wall because the distal end 15 of the inner needle 14 is very flexible, as illustrated, for example, in Figure 4 and corresponding text, or has an alternative tip 25, as illustrated, for example, in Figure 8 and corresponding text, when fully extended from the distal opening 18 of the outer needle 12. When the distal end 15 of the inner needle 14 contacts the left atrial free wall, the distal end 15 of the inner needle 14 harmlessly bends rather than perforates the left atrial free wall. In one embodiment, the distal end 15 of the inner needle 14 bends because of the enhanced flexibility of the inner needle 14 at the intermediate portion 16, as described above in connection with Figures 4-8, between the proximal portion 11 and distal portion 15 of the inner needle 14. In an embodiment, perforation of the left atrial wall is avoided by modifying the shape of the inner needle 14 to form, for example, a hook or a bend.

[0060] Another advantage of the transseptal puncture devices described herein is the ability of the device to puncture through thick septum such as septum secundum. The transseptal puncture devices according to the invention can be used for remote suturing of a PFO or other defects that may be accessed percutaneously.

[0061] The transseptal puncture device according to the invention can also be used with various atrial septal defect locators such as those described in U.S.S.N. 10/660,444. For example, the

locator may stabilize (*e.g.*, constrain) the motion of the septa during insertion of the inner needle. Generally, a locator system includes a plurality of flexible members, at least one flexible member positionable on a side of the tissue opposite to another flexible member.

[0062] Figure 10 illustrates a septal puncture apparatus 100 including three flexible members 142a, 142b, and 142c (generally 142) coupled to a delivery member 120 for applying, *e.g.*, a pressure or force to a region in a body by pushing, pulling, or restraining the tissue, thereby stabilizing the tissue. The flexible members 142a, 142b, and 142c may be hexagonal in shape and coupled to a distal end 124 of the delivery member 120, thereby forming, generally, a planar array 150. The delivery member 120 is slideably receivable within a lumen 110 of the elongate member 104. Instruments, *e.g.*, the delivery member 120 and a cutting member 300 (*e.g.*, a member that perforate the tissue, which can comprise, referring to Figure 1, an inner needle 14 and/or an outer needle 12, for example), are slideably receivable in the lumen 110 of the elongate member 104. In this embodiment, the cutting member 300 is slideably receivable in a lumen 308 of the delivery member 120 and extends distally or withdraws proximally from an opening 312 at the distal end 124 of the delivery member 120.

[0063] Figure 10 also illustrates an exemplary interface 130 that permits controllers, for example, a set of apparatus controllers 134 and 138 to communicate with the elongate member 104 and the delivery member 120, respectively. The exemplary controllers 134 and 138 extend, retract, or otherwise manipulate, *e.g.*, the elongate member 104 and the delivery member 120, respectively. A single controller, could, alternatively, control all functions and operations of the tissue puncture apparatus 100 and the instruments disposed therein.

[0064] By way of example, the elongate member 104 and the delivery member 120 are flexible tubes fabricated from a biocompatible material, *e.g.*, polyethylene, polyether-amide block copolymer (PEBAX™), polyurethane, or fluorinated ethylene propylene.

[0065] By way of example, the flexible members 142 are manufactured using nickel-titanium material, such as Nitinol™ (Nitinol Devices and Components, Fremont, CA), or other shape memory alloy materials. The nickel-titanium wire, when properly manufactured, exhibits elastic properties for the wire to be manipulated (*e.g.*, bent) by an operator and then returned to, substantially, the same shape the wire possessed prior to it being manipulated.

[0066] Alternatively, Figure 11 illustrates a portion of a septal puncture apparatus 100 including exemplary flexible members 142'a and 142'b, which each include a leg such as a wire having a first end 204'a and 204'b, respectively, joined to the distal end 124 of the delivery member 120. Each of the flexible members 142'a and 142'b also have a second distal end 202'a and 202'b, respectively, that is free, *i.e.*, not joined to any other structure of the septal puncture apparatus 100. The longitudinal axis of the flexible members 142'a and 142'b are oriented substantially parallel to the elongate member 104 when the flexible members 142'a and 142'b are located within the lumen 110 of the elongate member 104. The flexible members 142'a and 142'b have a first portion 272a and 272b, respectively and a second portion 270a and 270b, respectively. The flexible members 142'a and 142'b are disposed within the lumen 110 in a contracted position such that the second ends 202'a and 202'b are directed distally towards the opening 112 in the distal end 106 of the elongate member 104. The flexible members 142'a and 142'b are freed from the confines of the lumen 110 by moving the flexible members 142'a and 142'b between the contracted position illustrated, for example, in Figure 11 and an extended position, such as the extended position depicted in Figure 12B. After insertion into the lumen 110 of the elongate member 104, the flexible members 142'a and 142'b apply a force to an inner surface 210 of the elongate member 104 in a first location 230a and 230b, respectively, on the inner surface 210 of the lumen 110 that the flexible members 142'a and 142'b contact.

[0067] Referring now to Figure 12A, as the delivery member 120 is extended out of the opening 112 of the elongate member 104, the second ends 202'a and 202'b of the flexible members 142'a and 142'b, respectively, undergo an articulation and point, generally, in a proximal direction toward the handle (not shown). Referring now to Figure 12B, the elongated delivery member 120 is further extended distally along the lengthwise dimension (in the positive direction along the X-axis) of the lumen 110 until the distal end 124 of the delivery member 120 emerges from the opening 112 of the elongate member 104. The second ends 202'a and 202'b of the exemplary preshaped flexible members 142'a and 142'b, respectively, undergo an additional articulation and as a result point, generally, towards one another. In this extended position, each of the flexible members 142'a and 142'b is substantially planar in shape.

[0068] Alternatively, the second ends, for example, the second ends 202'a and 202'b, may have a different diameter than other locations along the length of the flexible elastic members 142'a and 142'b. By way of example, an operator may select an apparatus having flexible members that have second ends 202'a and 202'b having a larger diameter to, for example, reduce trauma to tissue the second ends 202'a and 202'b contact during use. Alternatively, the second ends 202'a and 202'b may have a ball shaped tip.

[0069] Figure 13 depicts exemplary flexible members 142''a and 142''b that include a first wire loop section 220a and a second loop section 220b, respectively. The tip 406a and 406b of the loop sections 220a and 220b, respectively, point, generally, towards one another and towards the delivery member 120. Loop sections 220a and 220b may, alternatively, be oriented in a variety of directions (*e.g.*, away from the delivery member 120 or at a 45 degree angle away from the delivery member 120).

[0070] Referring now to Figures 14A and 14B, a septal puncture apparatus 100 includes a single flexible member 142''' that has a middle section 540 located, generally, intermediate the first end

206 and the second end 208 of the flexible member 142'''. The flexible member 142''' thereby forms a closed loop. In this embodiment, the flexible member 142''' is configured so the middle section 540 is located, generally in the center of a plane defined by the flexible member 142''' as illustrated by the end-on view of Figure 14B. In this configuration, the middle section 540 of the flexible member 142''' aids with stiffening the flexible member 142''', which minimizes bending when, for example, the flexible member 142''' is used by an operator to apply forces to a tissue, *e.g.*, the atrial septum. In this configuration, the flexible member 142 forms a closed loop that is sized and shaped, for example, to contact a first and second side of a tissue.

[0071] Referring now to Figures 15A and 15B, the flexible elastic member 142'''' is a coil and has a spiral shape. By way of example, in use, a portion 1410 of the flexible member 142'''' can be located on a first side of a tissue and a portion 1420 of the flexible member 142'''' can be located on a second side of a tissue. For example, the flexible member 142'''' can be screwed through a tunnel or a hole, such as a defect in the atrial septum. Alternatively, the distal end 124 of the delivery member 120 may be located axially through, for example, a hole in a tissue such that the flexible member 142'''' may be withdrawn partially through the hole by a rotational (screw-like) motion of the delivery member 120 thereby locating the portion 1410 of the flexible member 142'''' on a first side of the tissue and the portion 1420 of the flexible member 142'''' on a second side of a tissue.

[0072] Referring to Figure 16A, the delivery member 120 is translated axially along the lengthwise dimension of the lumen 110 until the distal end 124 of the delivery member 120 emerges from an opening 112 in the elongate member 104 and the flexible members 142a, 142b, and 142c transition from the contracted first position 330 shown in Figure 16A to a second extended position 340 shown in Figure 16B. The exemplary flexible members 142a, 142b, and 142c expand to assume, for example, substantially hexagonal shapes upon emerging from the

opening 112 in the elongate member 104 and expanding. The extended flexible members 142a, 142b, and 142c are substantially planar. The plane defines a plurality of axes that lie in the plane and the plurality of axes are non-parallel to (i.e., biased relative to) the elongate member 104. An angle 344 defined by at least one of the plurality of axes of the plane of the flexible members 142a, 142b, and 142c and the longitudinal axis of the elongate member 104 is typically specified (e.g., by an operator) such that the flexible members 142a, 142b, and 142c are flush with tissue surface and are capable of applying a force across a large tissue area. For example, the angle 344 might be chosen to ensure the flexible members 142a, 142b, and 142c conform to the shape of a tissue surface abutting the flexible members 142a, 142b, and 142c. If the force is applied, e.g., across a large tissue area the movement of the tissue in any location across the tissue area will be minimized. The flexible members 142a, 142b, and 142c could, alternatively, be of any shape (e.g., polygonal, circular, or ellipsoidal) or of any quantity (e.g., one, two, or five) where the shape and/or quantity of the flexible members 142a, 142b, and 142c are typically selected to distribute as much force as possible while still being able to fit within the lumen 110 of the elongate member 104 and emerge from or retract into the lumen 110.

[0073] When the flexible members 142a, 142b, 142c are extended in the second expanded position 340 upon emerging from the opening 112, the exemplary cutting member 300 extends axially in the lumen 308 of the delivery member 120 until a cutting tip 304 of the cutting member 300 emerges from the opening 312 in the distal end 124 of the delivery member 120. The tip 304 of the cutting member 300 cuts the tissue in close proximity to the opening 312 of the delivery member 120.

[0074] Referring now to Figure 17, an operator introduces an elongate member 104 into the right atrium 748 of a heart 742 through the descending vena cava 750. The elongate member 104 is advanced distally until the distal end 106 of the elongate member 104 passes through a defect

620 (for example, a patent foramen ovale) in the septum 740. The distal end 106 of the elongate member 104 is shown at an angle 770 of about 45 degrees relative to the longitudinal axis of the elongate member 104 due to a bend 760 in the distal end of 106 of the elongate member 104. The bend 760 in the elongate member 104 may be mechanically pre-formed or pre-bent at the angle 770 between about 0 degrees and about 180 degrees prior to insertion of the elongate member into the body. The bend 760 could, alternatively, be accomplished by heating a nickel-titanium material or other shape memory alloy located within the distal end 106 of the elongate member 104.

[0075] The septal puncture apparatus shown in Figures 18A, 18B, and 18C includes two flexible members 142'a and 142'b coupled to the distal end 124 of the delivery member 120. The flexible members 142'a and 142'b are initially located within the lumen 110 of the elongate member 104. An operator initially guides the distal end of 106 of the elongate member 104 through the defect (hole) 620 such that the distal end 106 is located on a second side 820 (in the left atria of the heart) of the septum secundum 600 and septum primum 610. Now referring to Figure 18A, the operator then extends the flexible members 142'a and 142'b as described herein with respect to, for example, Figures 12A and 12B.

[0076] With continued reference to Figure 18A, the elongate member 104 is retracted proximally until the distal end 106 of the elongate member 104 passes back through the defect 620 and is positioned on the first side 810 of the septum 740.

[0077] The delivery member 120 is then retracted proximally so the second portions 270a and 270b of the flexible members 142'a and 142'b and the distal end 124 of the delivery member 120 are in close proximity to the defect 620, the septum primum 610, and the septum secundum 600 on the second side 820 of the septum 740.

[0078] Now referring to Figure 18B, as the delivery member 120 is further retracted proximally such that the distal end 124 of the delivery member 120 is withdrawn through the defect 620 until it is in contact with or in close proximity to the first surface 880 of the septum primum 610 on the first side 810 of the septum primum 610. The second portions 270a and 270b of the flexible members 142'a and 142'b are positioned, generally non-parallel to the longitudinal axis of the elongate member 104 and are in physical contact with at least the second surface 870 of the septum primum 610 on the second side 820 of the septum primum 610 and also partially located within the defect 620 in the septum 740. The first portions 272a and 272b of the flexible members 142'a and 142'b are located on the first side 810 of the septum 740. Accordingly, the flexible members 142'a and 142'b are sized and shaped for contact with the first side 810 and the second side 820 of the septum 740. The flexible members 142'a and 142'b are thus capable of limiting movement of the septum primum 610. Now referring to Figure 18C, the cutting member 300 is extended from the opening 312 in the distal end 124 of the delivery member 120. The cutting tip 304 of the cutting member 300 introduces a hole 1005 (tissue opening) through the septum primum 610.

[0079] Referring now to Figure 19, an exemplary flexible member 142 is attached to the distal end 124 of the delivery member 120, which extends from the opening 112 in the distal end 106 of the elongate member 104. The delivery member 120 and the elongate member 142 are located on the first side 810 of the septum secundum 600. The distal end 124 of the delivery member 120 is located in close proximity to the tissue surface of the septum secundum 600 on the first side 810 of the septum secundum 600. The flexible member 142 extends through the hole 620 between the septum primum 610 and the septum secundum 600 from the first side 810 to the second side 820. The first side 810 of the septum primum 610 opposes the second side 820 of the septum primum 610. The flexible member 142 is positioned so that the second end

202 and second portion 270 of the flexible member 142 are located on the second side 820 of the septum secundum 600 and the first portion 272 of the flexible member 142 is located on the first side 810 of the septum secundum 600. In this configuration, the flexible member 142 is thus capable of limiting movement of the septum secundum 600. In this embodiment only the septum secundum 600 is secured to limit movement. In alternative embodiments, however, the septum secundum 600 and/or the septum primum 610 may be secured to limit movement.

[0080] Additionally, it should be noted that Applicants intend any operable embodiments existing between the devices, methods and applications thereof disclosed in the illustrative embodiments described above to be considered within the scope of the inventions disclosed herein and, as such, claimable subject matter.

Equivalents

[0081] The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The foregoing embodiments are therefore to be considered in all respects illustrative rather than limiting on the invention described herein. Scope of the invention is thus indicated by the appended claims rather than by the foregoing description, and all changes that come within the meaning and range of equivalency of the claims are intended to be embraced therein.

Incorporation by Reference

[0082] All publications and patent documents cited in this application are incorporated by reference in their entirety for all purposes to the same extent as if the contents of each individual publication or patent document was incorporated herein.

What is claimed is:

Claims

- 1 1. A device for puncturing the atrial septum of a patient, comprising:
 - 2 a first, outer needle comprising a blunt distal end and a lumen longitudinally
 - 3 disposed therethrough; and
 - 4 a second, inner needle axially disposed in the lumen of the outer needle, the
 - 5 second needle comprising a proximal portion, an intermediate portion, and a distal
 - 6 portion, wherein the intermediate portion is flexible relative to the proximal portion or
 - 7 the distal portion of the inner needle.
- 1 2. The device of claim 1, wherein the intermediate portion comprises a polymer.
- 1 3. The device of claim 1, wherein the intermediate portion comprises a waist.
- 1 4. The device of claim 1, wherein the distal portion comprises a bend.
- 1 5. The device of claim 1, wherein the distal portion comprises a shape selected from
2 the group consisting of a taper, a helix, a curve, a cork screw, and a hook.
- 1 6. The device of claim 1, wherein the intermediate portion comprises a segment
2 about 5 mm to about 30 mm from the distal end of the inner needle.
- 1 7. The device of claim 1, wherein the intermediate portion comprises a segment of
2 about 20 mm from the distal end of the inner needle.
- 1 8. The device of claim 1, wherein the intermediate portion is about 0.5 mm to about
2 30 mm in length.
- 1 9. The device of claim 1, wherein the intermediate portion is about 2 mm in length.

1 10. The device of claim 1, wherein the intermediate portion is tapered.

1 11. The device of claim 3, wherein the waist is about 0.1 mm to about 0.5 mm in
2 diameter.

1 12. The device of claim 3, wherein the waist is about 0.1 mm to about 1 mm in
2 diameter.

1 13. A method for puncturing the atrial septum of a patient's heart, comprising:

2 accessing the right atrium via a vessel;

3 introducing into the right atrium a transeptal puncture device comprising
4 a first, outer needle comprising a blunt distal end and a lumen longitudinally
5 disposed therethrough, and a second, inner needle axially disposed in the lumen
6 of the outer needle, the inner needle comprising a proximal portion, an
7 intermediate portion, and a distal portion, wherein the intermediate portion is
8 flexible relative to the proximal portion or the distal portion;

9 contacting the outer needle with the atrial septum;

10 pushing the inner needle through the septum in advance of the outer
11 needle; and

12 withdrawing the transeptal puncture device.

1 14. The method of claim 13, wherein the transeptal puncture device further comprises
2 s sheath through which the outer needle is axially disposed and wherein the method further
3 comprises the step of advancing the sheath through the septum.

1 15. The method of claim 13, wherein the transeptal puncture device further comprises
2 a sheath through which the outer needle is axially disposed and wherein the method further
3 comprises the step of advancing the sheath through the septum and removing the outer needle.

1 16. The method of claim 13, further comprising the step of using a locator device to
2 anchor the atrial septum prior to puncture.

1 17. A device for puncturing the atrial septum of a patient, comprising:

2 a first, outer needle comprising a blunt distal end and a lumen longitudinally disposed
3 therethrough; and

4 a second, inner needle axially disposed in the lumen of the outer needle, the inner needle
5 comprising a distal portion that deviates from the linear path of the needle.

1 18. The device of claim 17, wherein the distal portion comprises a bend.

1 19. The device of claim 17, wherein the distal portion comprises a taper, a helical,
2 curved, cork screw, or hooked shape.

1 20. A device for puncturing the atrial septum of a patient, comprising:

2 a first, outer needle comprising a blunt distal end and a lumen longitudinally
3 disposed therethrough; and

4 a second, inner needle axially disposed in the lumen of the outer needle, the inner
5 needle comprising a proximal portion and a distal portion, wherein the diameter of the
6 distal portion is smaller than the diameter of the proximal portion.

1 21. The device of claim 20, further comprising an intermediate portion between the
2 distal portion and the proximal portion, wherein the intermediate portion is tapered.

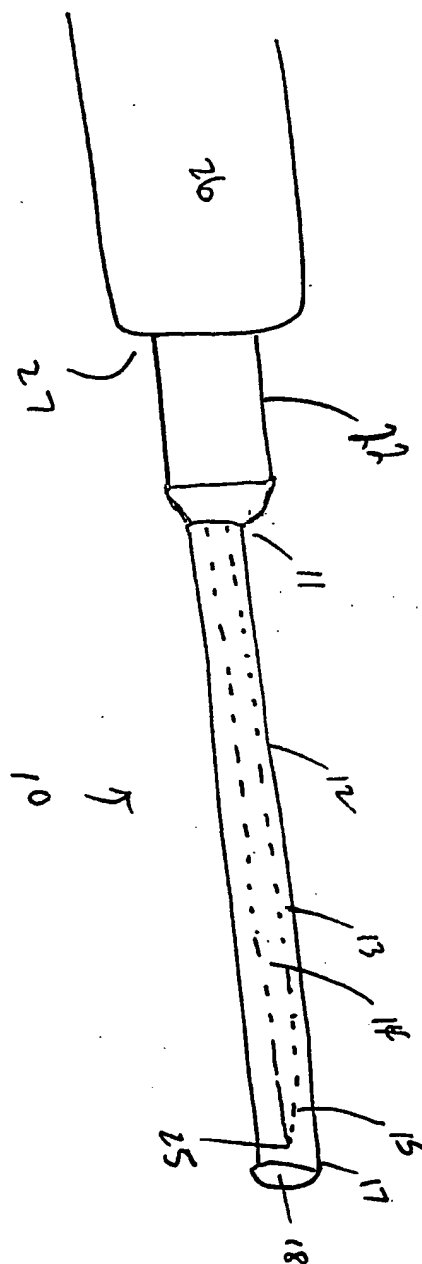


Figure 1

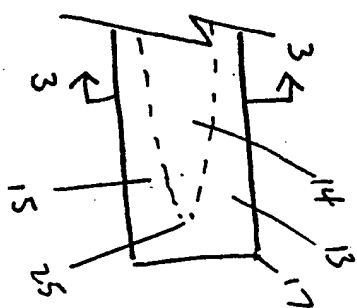


Figure 2

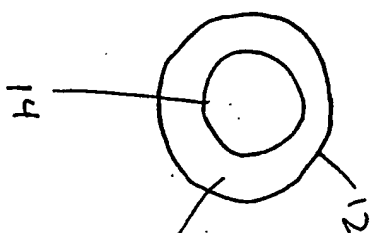


Figure 3

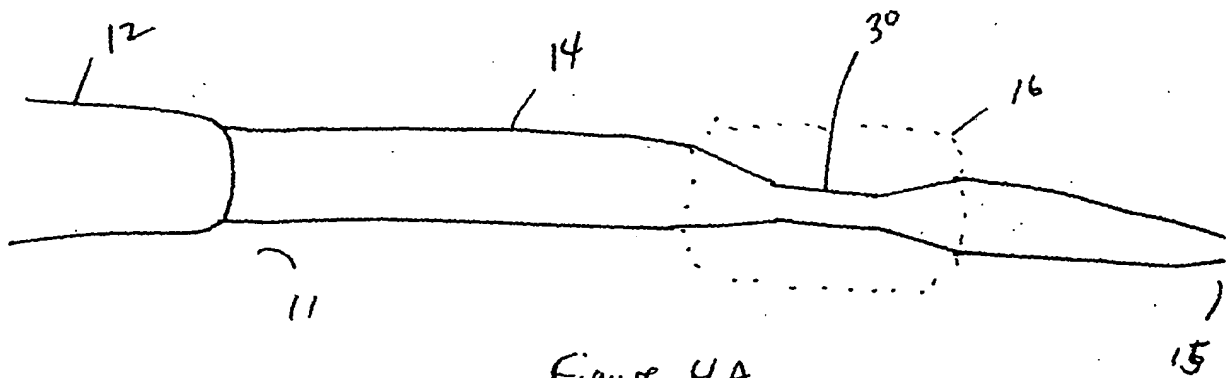


Figure 4A

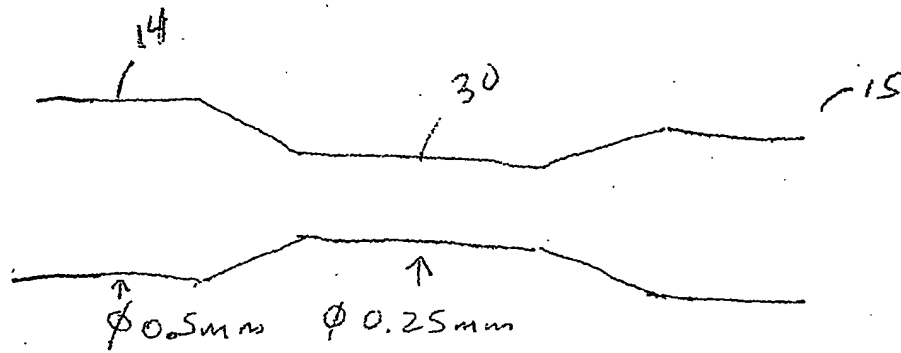


Figure 4B

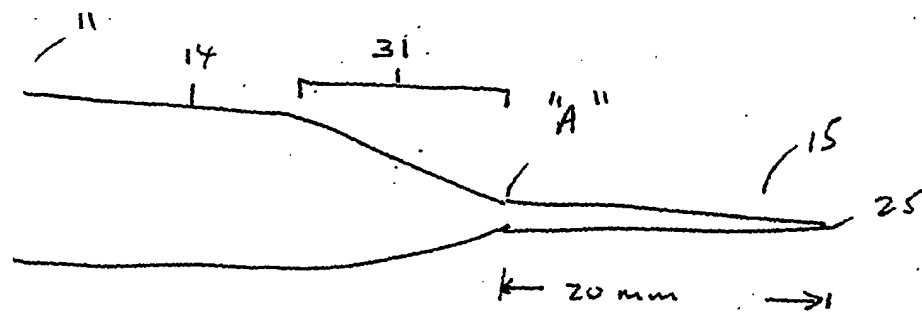


Figure 5

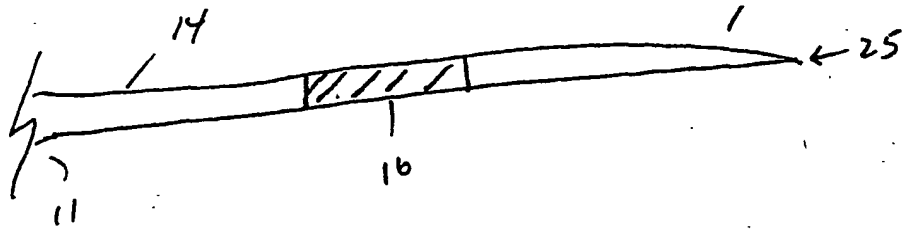


Figure 6

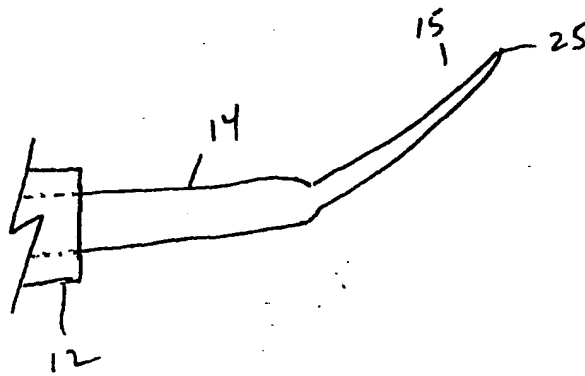


Figure 7

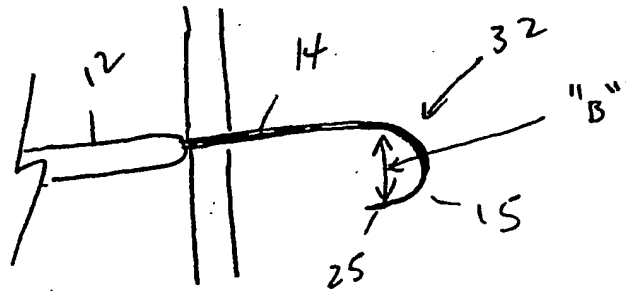


Figure 8

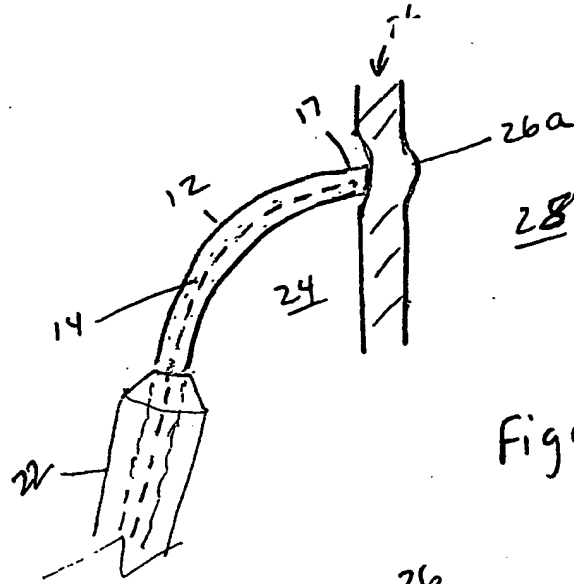


Figure 9A

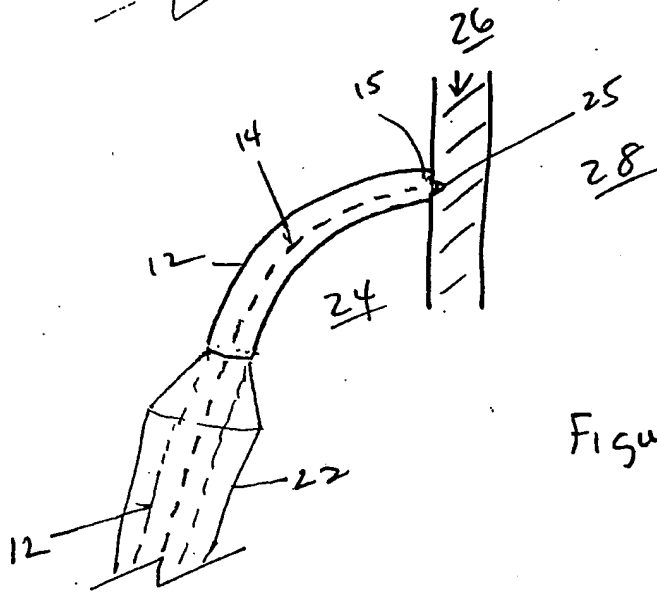


Figure 9B

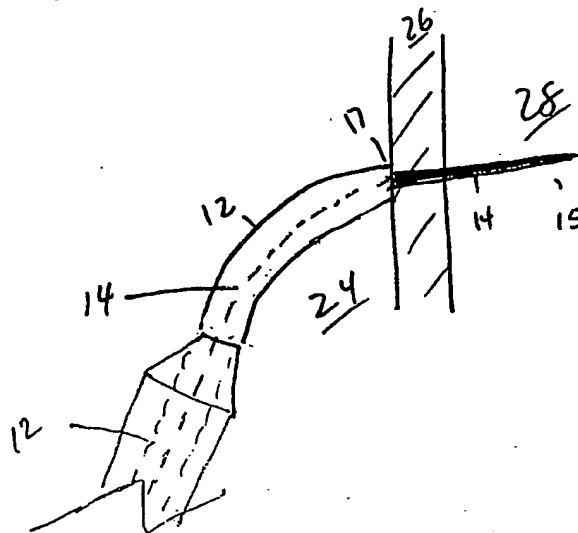


Figure 9C

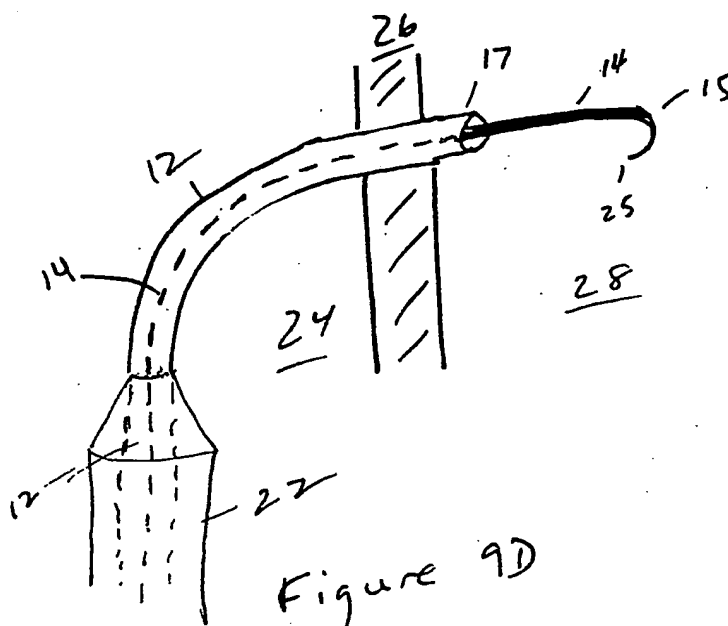


Figure 9D

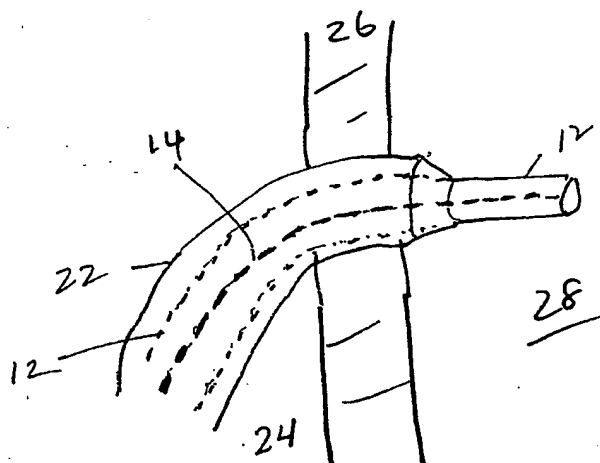


Figure 9E

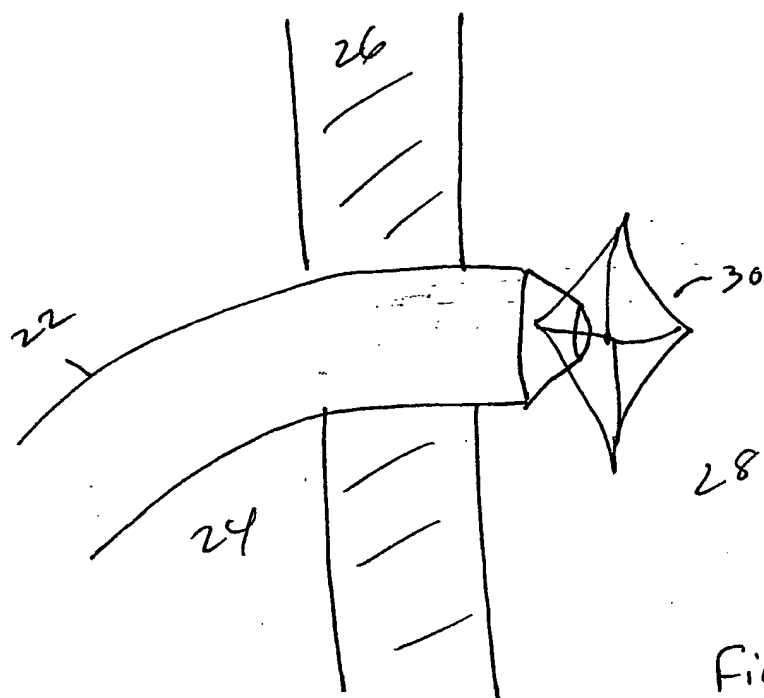


Figure 9F

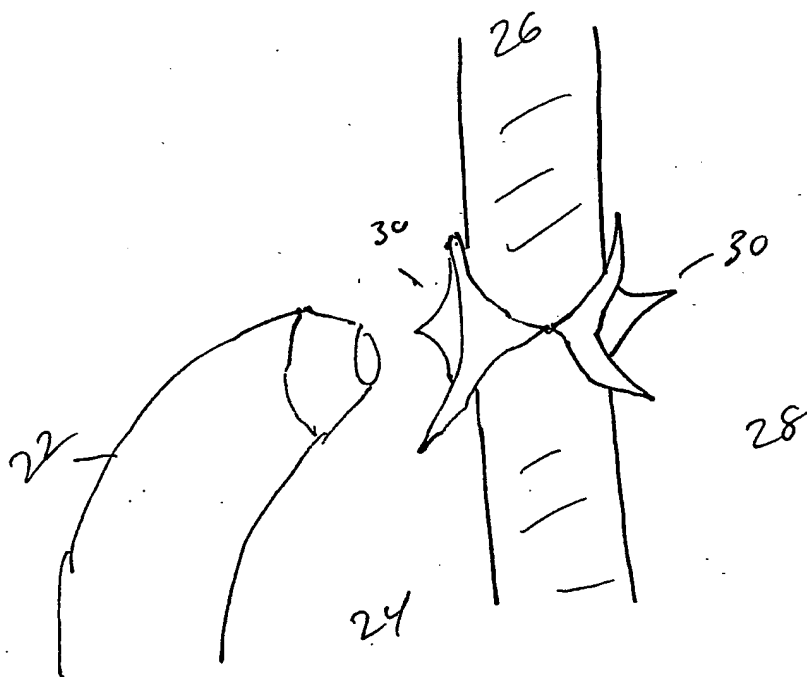


Figure 9G

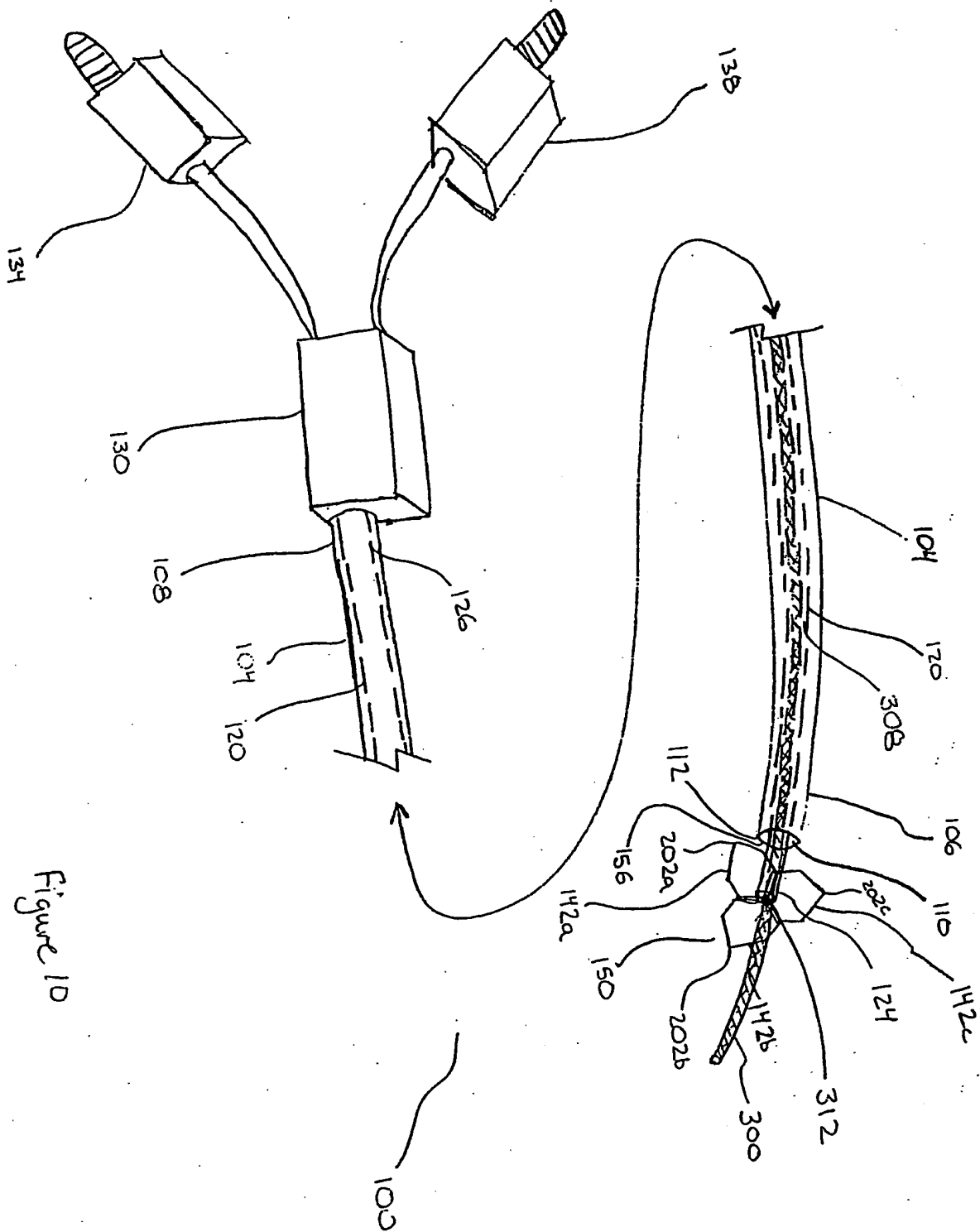


Figure 1D

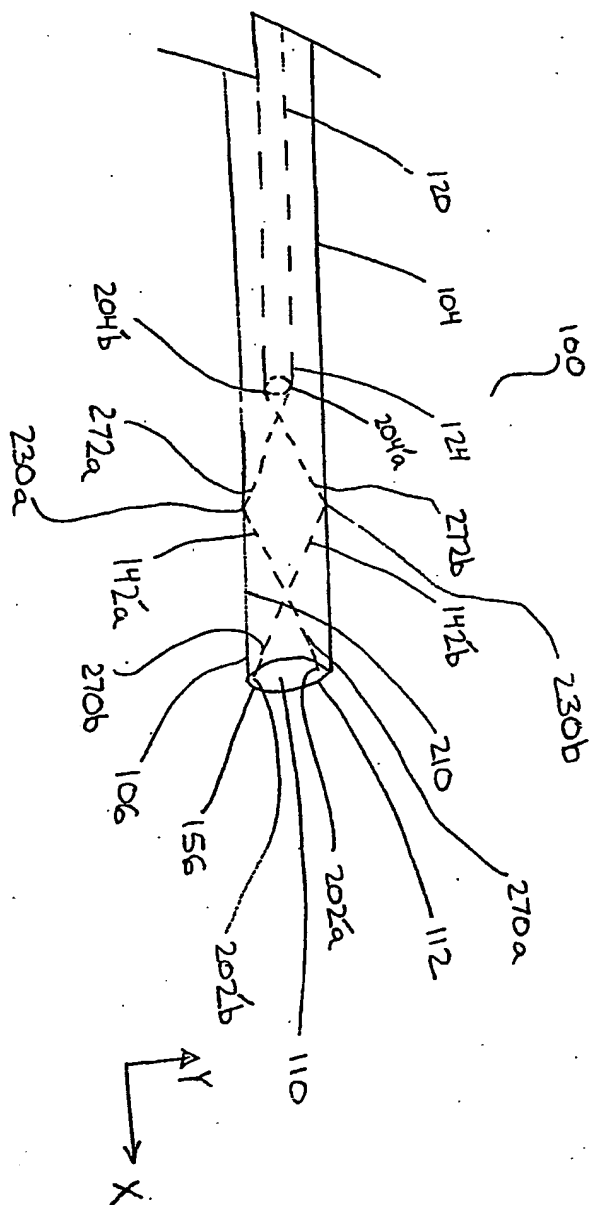


Figure 11

Figure 12A

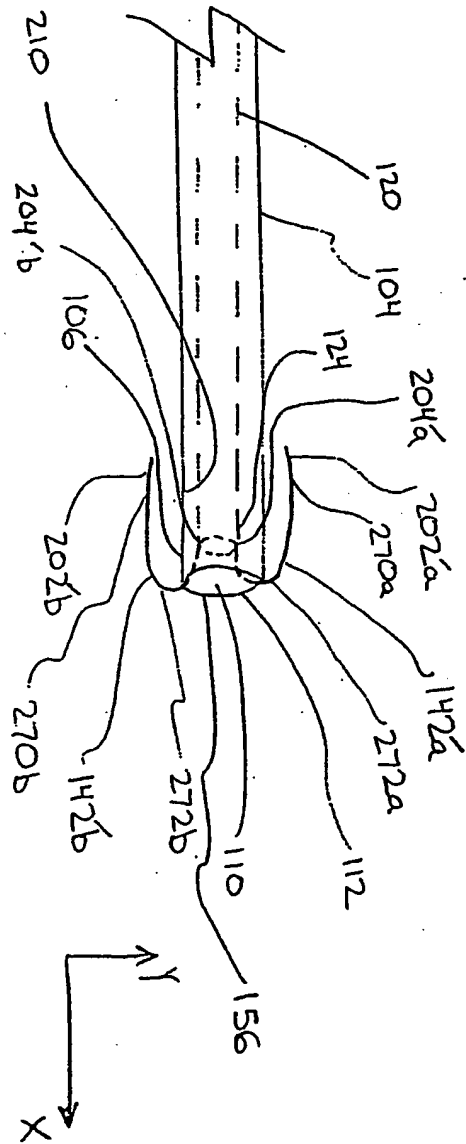
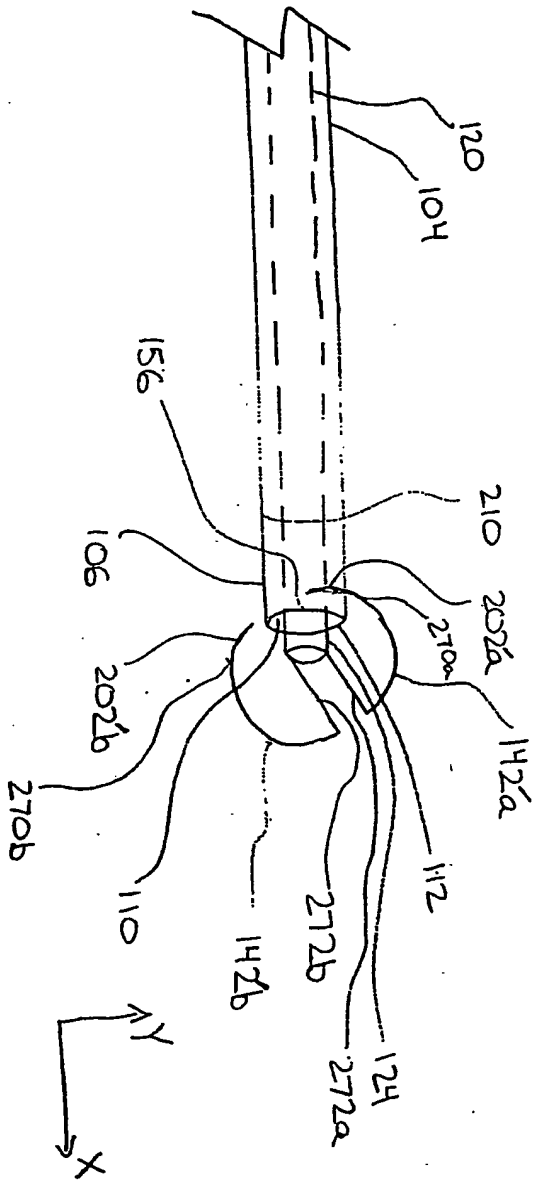


Figure 12B



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Figure 13

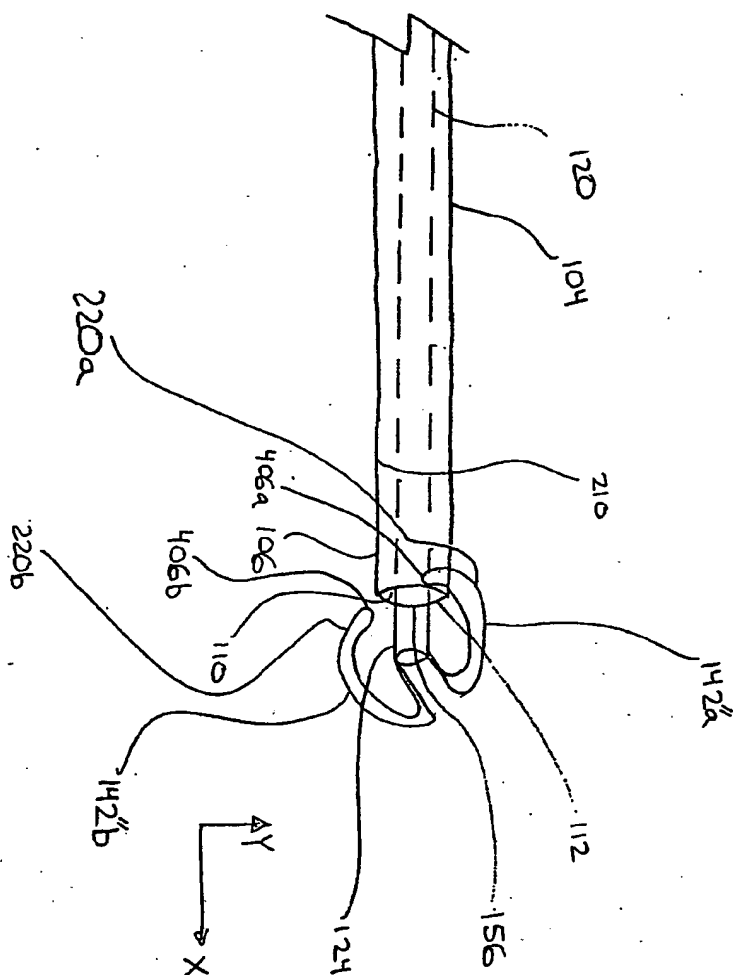


Figure 14A

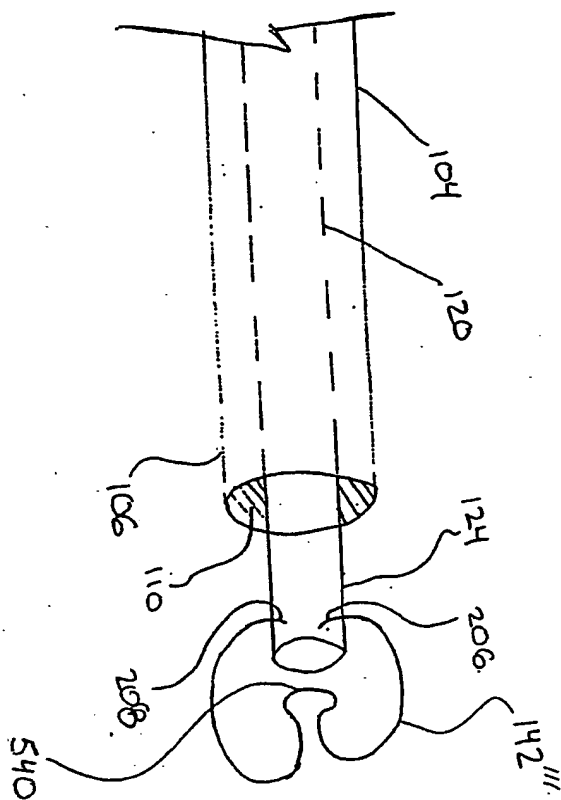
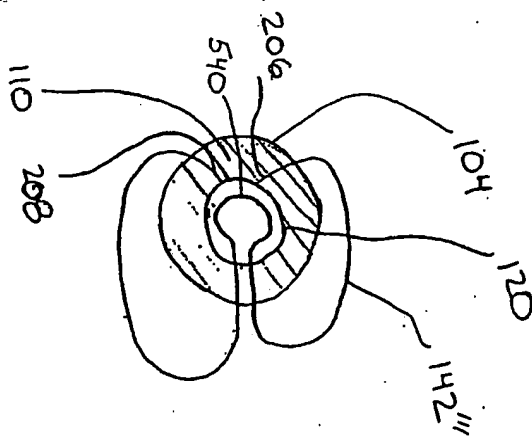


Figure 14B



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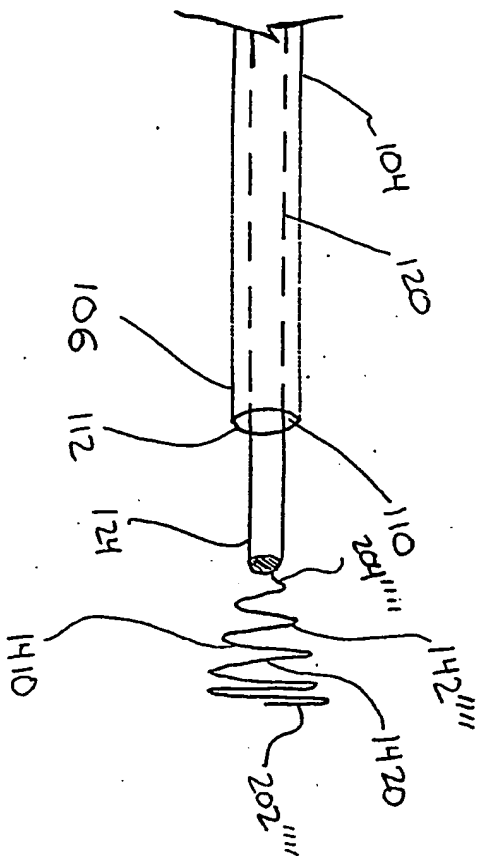


Figure 15A

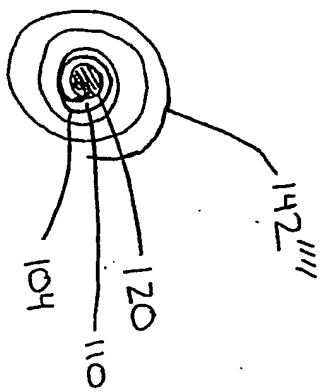
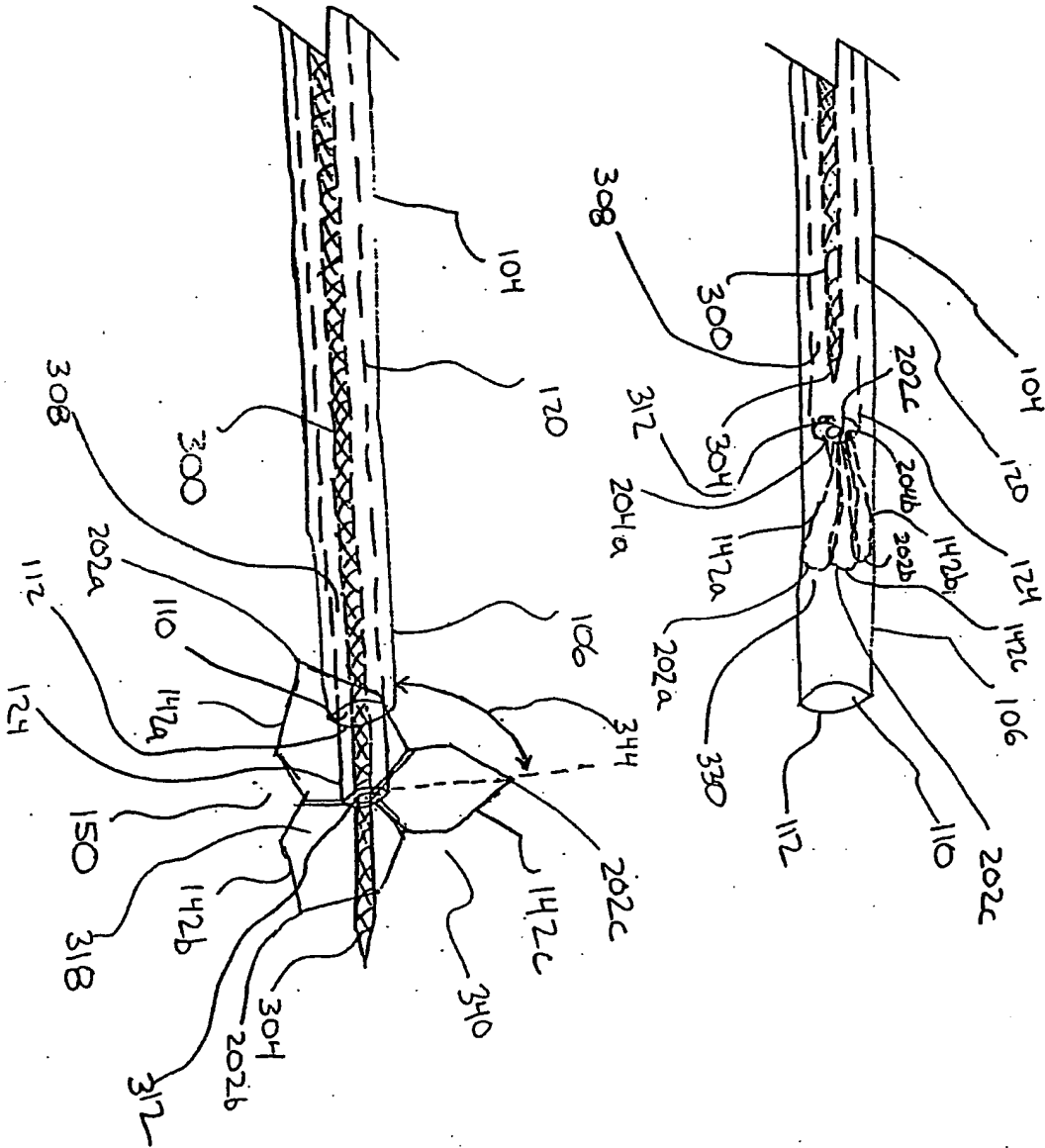


Figure 15B

Figure 16A

13/18

Figure 16B



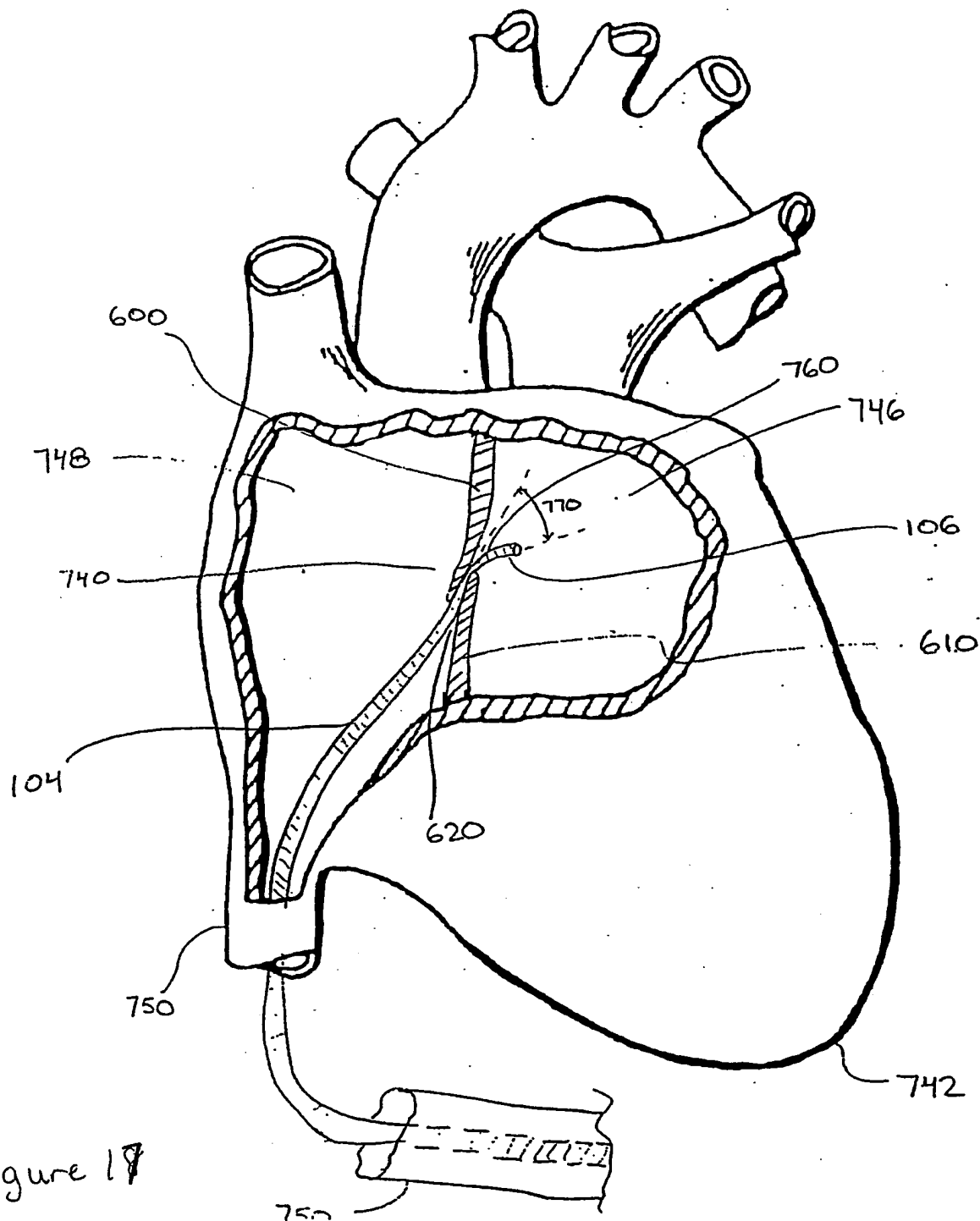


Figure 18

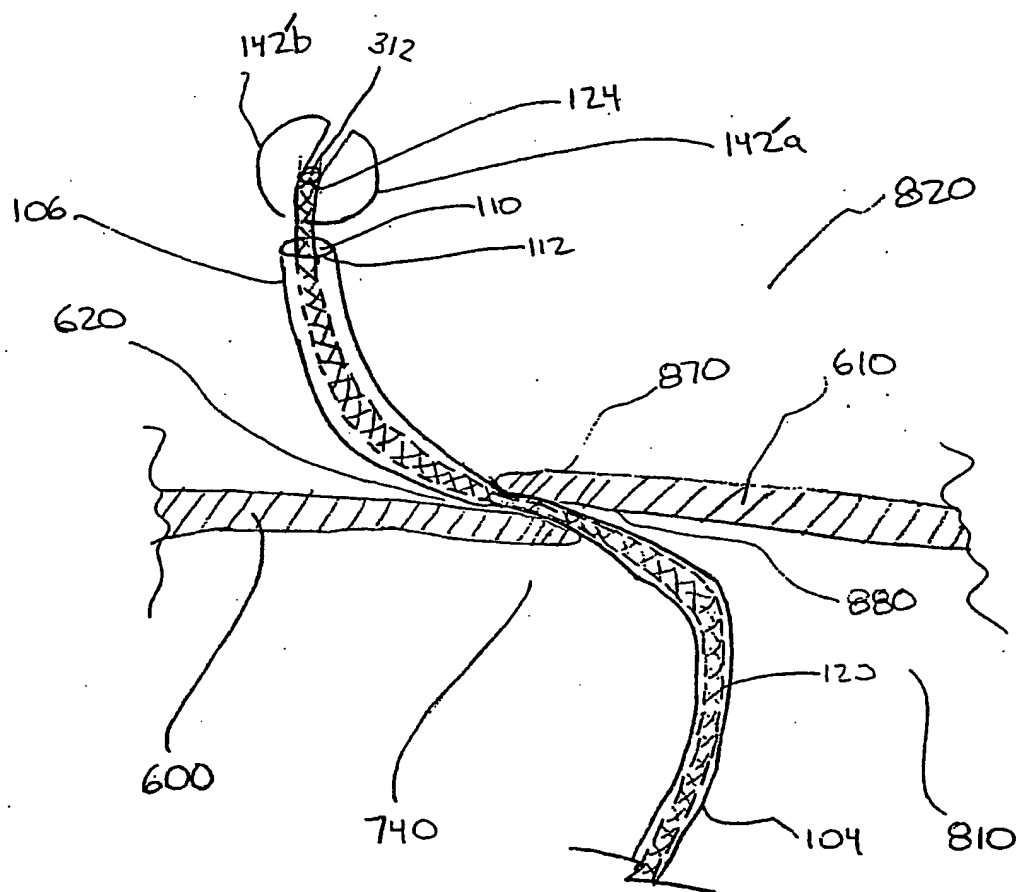


Figure 18A

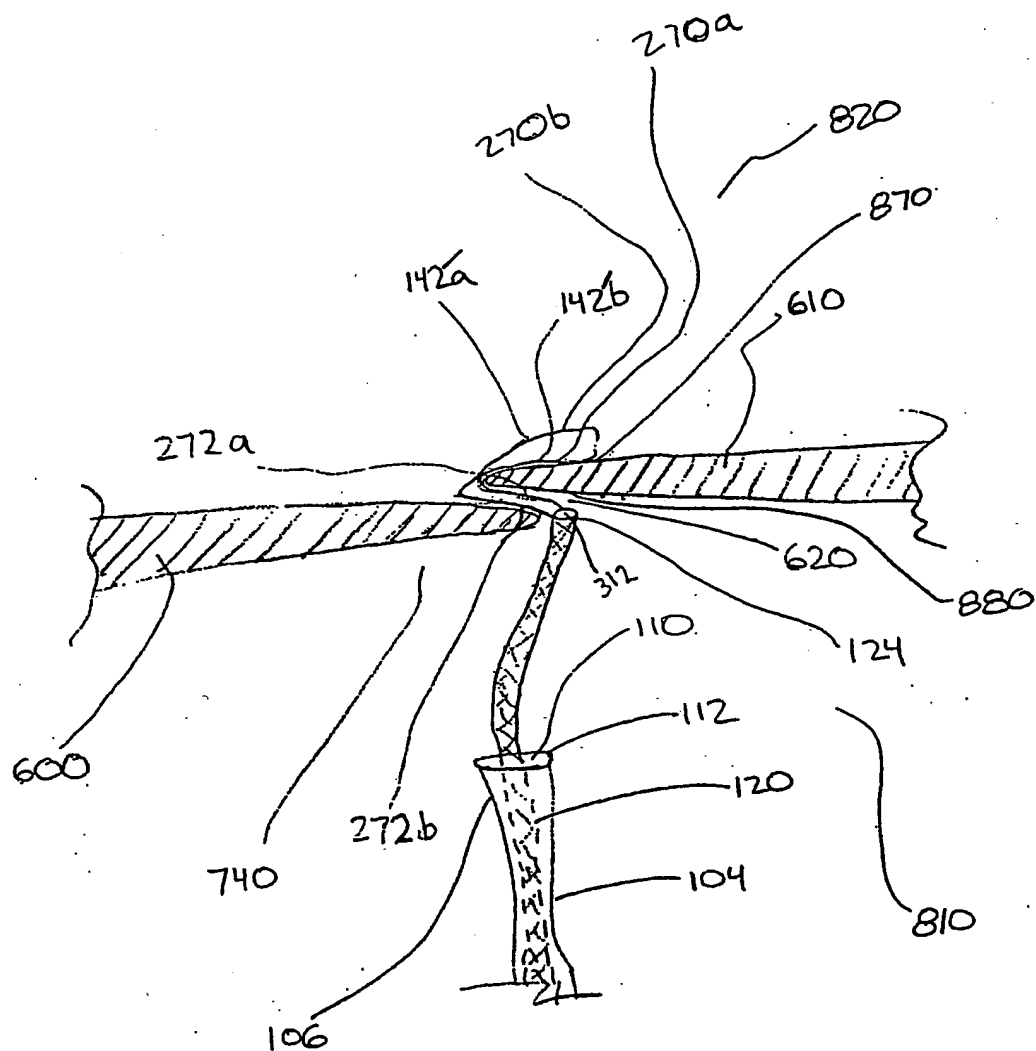


Figure 18B

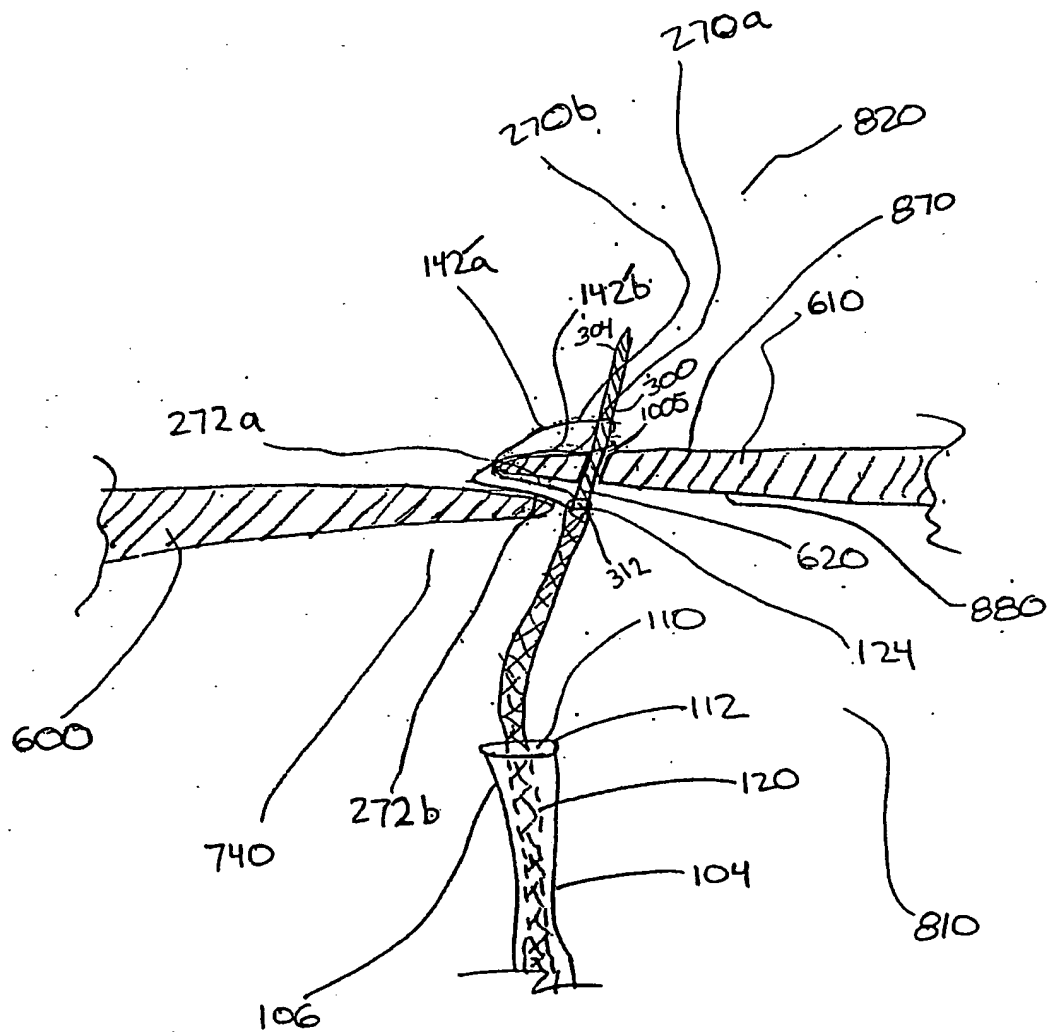
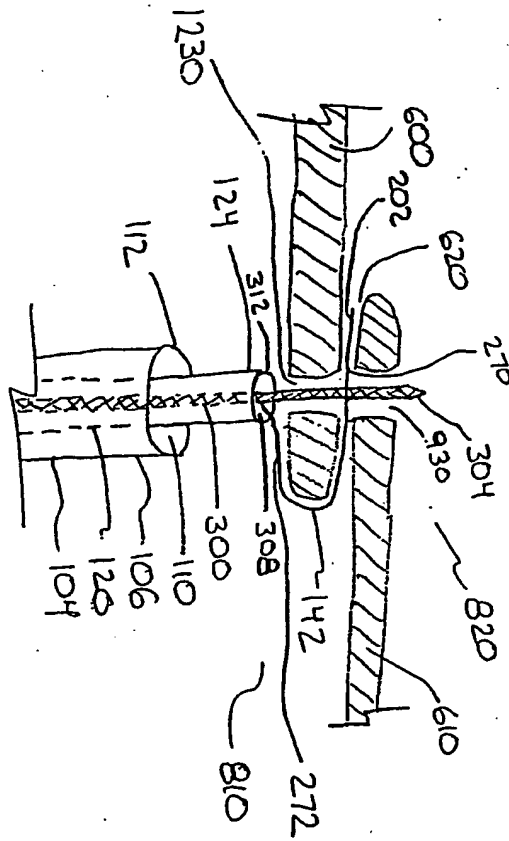


Figure 18C

Figure 19



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/014296

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/059152 A (NMT MEDICAL INC) 24 July 2003 (2003-07-24) page 1, paragraph 1 page 2, paragraph 7 - page 3, paragraph 10 page 7, paragraph 36 figures 5A,6,7,11C,11D	1,4-9, 17-20
Y	-----	2,3
X	WO 99/25254 A (APPLIED MED RESOURCES) 27 May 1999 (1999-05-27) page 1, lines 8-19 page 11, lines 14-31 page 21, lines 13-18 page 30, lines 7-17 figure 65 ----- -/--	1,4,5, 10,17-21

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

17 September 2004

Date of mailing of the international search report

24/09/2004

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Authorized officer

Kakoullis, M

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/014296

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/195531 A1 (GANDIONCO ISIDRO MATIAS ET AL) 16 October 2003 (2003-10-16) page 1, paragraph 4 page 3, paragraph 42	2
A	-----	1
Y	US 6 325 807 B1 (QUE LIKE) 4 December 2001 (2001-12-04) column 1, lines 10-17 column 6, lines 26-54 figure 7A	3
A	-----	1
A	US 5 573 542 A (STEVENS JON A) 12 November 1996 (1996-11-12) the whole document	1,4,5, 17-20
A	-----	
A	US 6 258 026 B1 (KLESHINSKI STEPHEN J ET AL) 10 July 2001 (2001-07-10) column 8, lines 29-50	1
A	-----	
A	US 6 001 085 A (OCKULY JOHN DAVID ET AL) 14 December 1999 (1999-12-14) column 1, lines 10-34 column 4, line 44 - column 5, line 17 figures 2,3	1,4,5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/014296

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 13-16
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/014296

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